What would I find in your TMF?

Top 10 problems

and the best practices to avoid them



Daniel Bennett 20 May 2022 0.2 20220505

Disclaimer

These views are my own, and not necessarily those of my employer, past, present or future.





Second Disclaimer

These are common *almost universal* issues.

Please do not assume I am talking about a particular situation, sponsor, CRO or trial.

I have seen each of these *dozens* of times in dozens of different circumstances.

1) Ethics is incomplete



Sometimes very incomplete

Review the dialogue

EEK

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Artifact Number	Artifact Name	Subartifact	Date	Detail
04.01.01	Ethics Submission	Cover Letter	05 Jun 2018	Initial Submission. Protocol V1.0 17Apr2018. Main ICF V1.1.0 24May2018.
04.01.01	Ethics Submission	Submission	05 Jun 2018	Initial Submission. Protocol V1.0 17Apr2018. Main ICF V1.1.0 24May2018.
04.01.01	Ethics Submission	Acknowledgement of Receipt	06 Jun 2018	Initial Submission 05Jun2018.
04.01.01	Ethics Submission	Query	25 Jun 2018	
04.01.01	Ethics Submission	Query Response	03 Jul 2018	Query 25Jun2018. Main ICF V1.2.0 02Jul2018.
04.01.02	Ethics Decision	Approval	03 Aug 2018	Initial Approval. Protocol V1.0 17Apr2018. Main ICF V1.2.0 02Jul2018.
04.01.01	Ethics Submission	Cover Letter	02 Feb 2019	Substantial Amendment 1. Protocol V2.0 26Jan2019. Main ICF V2.1.0. 27Jan2019.
04.01.01	Ethics Submission	Submission	02 Feb 2019	Substantial Amendment 1. Protocol V2.0 26Jan2019. Main ICF V2.1.0. 27Jan2019.
04.01.02	Ethics Decision	Approval	04 Mar 2019	Substantial Amendment 1. Protocol V2.0 26Jan2019. Main ICF V2.1.0. 27Jan2019.
04.01.01	Ethics Submission	Notification	21 Apr 2019	IB Ed.17 20Apr2019.
04.01.01	Ethics Submission	Acknowledgement of Receipt	21 Apr 2019	Notification 21Apr2019
04.01.01	Ethics Submission	Cover Letter	24 Jan 2020	Substantial Amendment 2. Main ICF V2.2.0. 23Jan2020. Pregnancy ICF V1.1.0. 16Jan2020
04.01.01	Ethics Submission	Submission	24 Jan 2020	Substantial Amendment 2. Main ICF V2.2.0. 23Jan2020. Pregnancy ICF V1.1.0. 16Jan2020
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05 Jun 2018	Cover Letter				
05 Jun 2018	Submission	06 Jun 2018	AoR	25 Jun 2018	Query
03 Jul 2018	Query Response			03 Aug 2018	Approval
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02 Feb 2019	Cover Letter				
02 Feb 2019	Submission			04 Mar 2019	Approval
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21 Apr 2019	Notification	21 Apr 2019	AoR		
24 Jan 2020	Cover Letter				
24 Jan 2020	Submission	24 Jan 2020	AoR	26 Feb 2020	Approval
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Things missing from this simplified example:

- There would be more things in the initial submission.
- Expiry Date for the Approval.
- Metadata field for 'Initial'.
- Submission Package QC & Approval Forms.
- Substantiality Assessment Forms.



2) Regs is incomplete Exactly the same as for ethics



3) Site stops suddenly

We need more documents

Clarissa Pinkula Estés Kalevala

4) Filenotes pointing at problems

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Rethaus

Fest

Bahnhof

OBI

Schulen

Friedhol

Kirchen



5) Central ethics vs local ethics





6) Site Delegation Log with awful corrections





8) Gaps in a sequence

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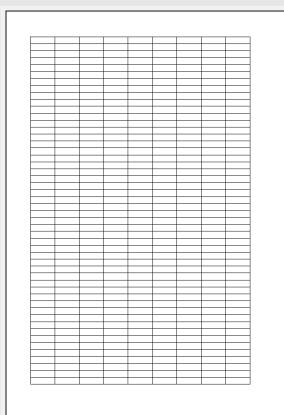
H) Inconsistency

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Version	Parent
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Lifecycle Stage	Data Privacy
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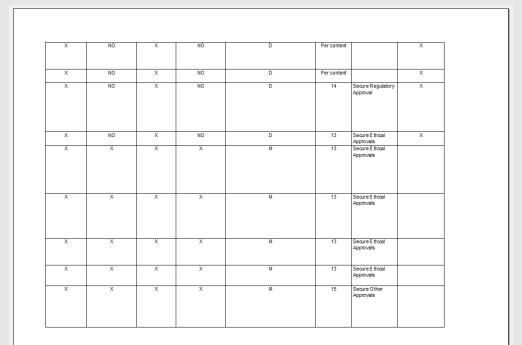


9) Autopaginated documents & broken tables

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2022



Technical Wizardry

Excel is different to Word. In Word if you want a bigger page you can define any custom size. In Excel to do the same thing you need a printer driver.

I recommend:



Canon Pro 4100 SR 44" 12 Colour Printer

Unrivalled colour expression with fast and efficient 44inch output. Highly productive, precision printing for head-turning visuals Achieve flawless photographic and fine art printing every time. Intelligent configuration Read More

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£5,994.00

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Sow Stock / Out Of Stock – Call Or Email To Confirm Stock Level.





You do not need the printer, just the free to download driver.



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10) Hidden treasure



Bonus: versioning

- 1,2,3,4,5,6,7,8,etc
- 1.0, 2.0, 3.0 etc for final versions
- 0.01, 3.02 etc for drafts
- 1.1.1 for documents at all three levels

Have you got widely shared written instructions and understanding on how to version control documents?





